

PATENT APPLICATION**Portable Handheld Hearing Screening Device and Method****With Internet Access And Link to Hearing Screening Database****Inventor(s):**

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**Portable Handheld Hearing Screening Device and Method With
Internet Access And Link to Hearing Screening Database**

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Related Applications

This application is a continuation-in-part of the continuation-in-part application entitled "Portable Handheld Hearing Screening Device and Method With Internet Access and Link to Hearing Screening Database" Serial No. 10 10/254,294 filed 9/25/2002 of the Provisional Patent Application Serial No. 60/326,628 entitled "Portable Handheld Hearing Screening Device and Method with Internet Access and Link to Hearing Screening Database" filed 10/2/01, now abandoned.

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Background of the Invention

Field. This invention pertains to hearing screening devices. In particular, it pertains to a hearing screening device employing handheld detectors of
5 otoacoustic emissions or auditory brain responses, which transmit them to a remote central computer server. The remote central computer server analyses the signals and transmits them to an audiologic screen device, which displays the otoacoustic signals or electric brain responses to determine whether they are or are not significant. These signals can also be analyzed and displayed by the handheld
10 device as well.

State of the Art. Hearing Screening, especially on neonates, often takes place in environments, where a personal computer (PC) is not easily available, such as in a maternity clinic, NICU, etc., or, it is conducted by staff who are not very familiar to work with PC-SW. Screening programs should be easy to
15 conduct. They should be able to deliver consistent results independent of the user. It should be a quick operation for personal (doctors, nurses), parents and neonates.

In order to fulfill these requirements, handheld, stand-alone screening devices have been developed. Today, many regional and/or statewide hearing screening programs will be implemented soon within Europe, Japan, USA, and
20 many other countries all over the world.

Hearing screening programs require patient tracking & follow up diagnostic procedures. A screening test will deliver a “Pass”/“Refer” result without indicating in detail the hearing disorder. Therefore, after a “refer” result, a more detailed diagnostic is necessary. This normally is done by an audiologist or an ENT expert using more sophisticated diagnostic equipment. In most cases, these experts and specialized equipment are located in a different clinic or hospital.

Also there is an increasing need for statistical evaluation of the overall screening results requested by the region or the state. Therefore, all results of a screening program need to be transmitted to some central ‘Patient Tracking System’, which most probably is also located far from the screening location.

Furthermore “quality assurance programs” need to be introduced in order to guarantee that the correct result will be linked to a person. Therefore “safe” data transfer from the single screening device to the central data logging computer (often only one per region) is required.

In order to fulfill these requirements many of the new screening devices can be hooked up to a PC or Laptop, which then transfer the screening results in a second step to the central ‘Patient tracking system’. Unfortunately, this approach again requires PC knowledge, which can be avoided by introducing the handheld, stand-alone screening devices. Currently, many handheld hearing screening devices, such as the handheld audiological screening device produced by Fischer-Zoth GmbH under its “echo-screen” trademark, are able to transfer the test result to a local PC or Laptop, either via a cable connection, infrared or other methods, like “blue tooth”. The local PC then synchronizes – in a second step – its data with a central “Patient tracking database” located on a remote, central computer. This could be done by sending the data from PC to the central computer via a global communication link, internet, modem connection or other methods. As mentioned, these handheld devices are simple to use, but do not allow the user to

enter additional data, transfer the data directly to the "Screening database" or have any direct communication with that database.

To avoid these limitations, a handheld signal transmitting screening device, and receiver associated with a signal analysis database is required to
5 translate the signals and transmit them back to the user. The device and method described below provides such an invention.

Summary of the Invention

In clinical practice, it is important to transfer the screening results to a tracking system or database quickly and easily. The invention accomplishing these objectives comprises a handheld stand alone screening device and method
5 for using the same, which is adapted to hook up via a modem, network card, bluetooth interface or any other interface with data transmission networks and mediums such as terrestrial and wireless phone networks, optical data transmission networks, local area networks (LAN), wide area networks (WAN). It will communicate directly and autarkic (without means of a PC, Laptop, or
10 personal organizer) with a local or remote server or computer, which handles and records all patient related data. This also allows the access of many screening devices to one local database, either sequentially or contemporaneously.

The device is also capable of receiving the necessary patient data directly from the database stored in the remote or local server. After the local hearing
15 screening measurement has been completed successfully, the device enables a user to dial in directly into the transmission network (terrestrial or wireless phone network) and download the test results into the server. This connection could be done by a dialup connection via a built-in or attached modem (analog, ISDN etc.), via a connection to a local area network (LAN) or wide area network (WAN) or
20 other techniques. The modem connection generally includes the use of mobile phones and the direct access to the internet or intranet. The modem can be any external modem connected to the device or can be built into the device itself.

The objective is to eliminate the use of a local computer and its own operative software for the translating connection. An example of a preferred
25 embodiment of the device and system is that produced by Fischer-Zoth GmbH, which is a handheld OAE and/or ABR Screening device having at least one acoustic transmitter structured for generating one or more stimuli at sound frequencies in each ear canal of an infant, which generate responsive otoacoustic

emissions in both ear canals of the infant or newborn. At least one microphone is included and adapted to be removably placed in both ear canals for collecting any transient evoked and distortion product otoacoustic emissions generated by the cochlea in each ear canal in response to the stimulus to generate a frequency mixed product electronic signal. In addition, collection means, such as three electrodes placed onto the scalp, collect any click or frequency stimulated brain responses. A digital signal processor is associated with the microphone and electrodes to analyze their electronic signals. It is programmed with statistical processing instructions to statistically evaluate acoustic signal components by means such as binomial statistics to determine whether a measured signal contains stimuli elicited components for each frequency on a defined level of significance. An input device is included and associated with the microphones for inputting the frequency mixed product electronic signals and the stimulus frequencies into an incorporated computer processor. The device has an amplifier associated with the computer processor for amplifying the frequency mixed product electronic signals. A frequency analyzer and phase analyzer is associated with the computer processor to analyze a measured acoustic signal and separate the different frequencies and phases from one another. A display for displaying if the otoacoustic signal responses are or are not statistically significant may be included. In addition, a receiver may be included for displaying on the handheld screening device all patient related data, such as the infant patient's name, mother's name, birth date, address, in/outpatient, status, patient identification, hospital identification, patient history, etc. A modem (built-in, external, or plug-in) or external network adapter then transmits the handheld OAE and/or ABR response data, such as environmental noise, probe fit, electrode impedance, signal to noise ratio, etc, to an external database server. An external or internal power source is associated with the computer components, microphones, transmitters, amplifiers, display means, electrodes, modem or external network adapter to

operate the same.

The device and system is typically used as described below in the description of the illustrated embodiments.

The invention thus solves the problems with existing handheld systems and provides the following advantages:

- No local PC is needed.
- No software is to be installed on local computers, therefore no problems are to be expected concerning the operating system requirements
- No hardware problems are to be expected concerning the ports and other hardware that may vary in local computers.
- A data transfer could be initiated at any location where a phone connection, a mobile phone, an LAN socket, a wireless LAN or similar is available from virtually anywhere.
- The user only needs to initiate the connection to the central server, the server than can take control and retrieve the measurement data, send patient list data, send messages to the user that are displayed directly, synchronize the real time clock, do software upgrades and other functions.
- No problems occur regarding which data is on which computer. A central server that is contacted directly (or via any kind of proxy) by the device holds all data. Patient data security is managed much easier.
- The central server can react on the data that is transferred, for example by sending appropriate messages if a measurement was not performed correctly.

Description of the Drawings

Fig. 1 is a schematic of an embodiment of the invention connected to a central server vial modem.

5 Fig. 2 is a schematic of the embodiment of the invention associated with a server via a local network.

Fig. 3 is a schematic of an embodiment of the invention connected to a main server.

10 Fig. 4 is a schematic of embodiments of the invention associated with regional servers.

Description of the Illustrated Embodiments.

Fig. 1 illustrates the handheld screening devices connect to a central server via local modems. The screening devices communicate with a central server by actively establishing a dial-up or other connection. The handheld unit is able to store and memorize predefined phone numbers or these phone numbers can be entered via a keyboard similar to a handheld phone. The connection can be established via an analog or digital phone linen, via cordless or cellular phone channels or other media, such as power lines, fiber optic connections, etc. The modem can either be either external with power supplied from the screening device or an independent source, or internal. No local PC is needed. Nor does the user need to use any other device then the screener itself.

Fig. 2 illustrates how the portable screening devices contact a server via local networks. The connection to the server could also be established through a local area network (LAN), which may be Ethernet, 'bluetooth' (wireless standard) or any other local area network. The screening device establishes the connection without the user having to use any software on a local PC. Thus the screening device has a distinct advantage over other screening devices currently available on the market, which need a local PC to transfer data from the device.

Fig. 3 illustrates how the portable screening devices use global information network (internet) services to connect to the main server. Internet /Intranet services can be used in order to connect the screening device to the remote Server. The device can be connected to an Internet service provider via a telephone line or ia WAP services (wireless application protocol). Measurement data and patient data can be exchanged on a special designed home page.

Fig. 4 illustrates the portable screening devices associated with Regional-Servers or WAN-servers used to de-centralize the data management.

These four figures illustrate a number of different set-ups to operate the handheld screening devices. The server side can be separated into a central server

and several 'regional' servers to optimise data handling even in nationwide data management systems. Each regional server is connected to a certain number of devices, which are assigned thereto. The information as to which server to call and how to identify the server can be programmed by the screener. This programming
5 can also be done by a supplier so that the end user does not need to configure the system.

The connection can then also be used for various other actions besides transferring measurement data:

- Send patient lists to the screener
- 10 - update or change configuration information on the devices
- transfer and install new software on the screener
- setting the real time clock of the screener
- transferring messages to the user, patient related, device related and service instructions

15 The service-issues messages may be dependent on measurement results. For example, if the refer-rate is too high, the server could recommend a recalibration of the instrument.

Although this specification has made reference to the illustrated embodiments, it is not intended to restrict the scope of the appended claims. The
20 claims themselves recite those features deemed essential to the invention.